

§ 178.3530

21 CFR Ch. I (4–1–01 Edition)

achieve the desired functional effect but in no event in excess of any limitation prescribed, with or without subse-

quent treatment as authorized in §172.892 of this chapter.

List of reactants	Limitations
Ammonium persulfate, not to exceed 0.3 pct. or in alkaline starch not to exceed 0.6 pct. (4-Chlorobutene-2) trimethylammonium chloride, not to exceed 5 pct. β-Diethylaminoethyl chloride hydrochloride, not to exceed 4 pct. Dimethylaminoethyl methacrylate, not to exceed 3 pct. Dimethylol ethylene urea, not to exceed 0.375 pct	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging. Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
2,3-Epoxypropyltrimethylammonium chloride, not to exceed 5 pct. Ethylene oxide, not to exceed 3 pct of reacted ethylene oxide in finished product. Phosphoric acid, not to exceed 6 pct and urea, not to exceed 20 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging and as surface sizing and coating for paper and paperboard that contact food only of Types IV-A, V, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter.

(2) A starch irradiated under one of the following conditions to produce free radicals for subsequent graft polymerization with the reactants listed in this paragraph (a)(2):

(i) Radiation from a sealed cobalt 60 source, maximum absorbed dose not to exceed 5.0 megarads.

(ii) An electron beam source at a maximum energy of 7 million electron volts of ionizing radiation, maximum absorbed dose not to exceed 5.0 megarads.

List of reactants	Limitations
Acrylamide and [2-(methacryloyloxy) ethyl]trimethylammonium methyl sulfate, such that the finished industrial starch-modified shall contain: 1. Not more than 60 weight percent vinyl copolymer (of which not more than 32 weight percent is [2-(methacryloyloxy)ethyl] trimethylammonium methyl sulfate). 2. Not more than 0.20 pct residual acrylamide. 3. A minimum nitrogen content of 9.0 pct.	For use only as a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact food, and used at a level not to exceed 0.25 pct by weight of the finished dry paper and paperboard fibers.

(b) The following adjuvants may be used as surface-active agents in the processing of industrial starch-modified:

Polyethylene glycol (400) dilaurate.
Polyethylene glycol (400) monolaurate.
Polyoxyethylene (4) lauryl ether.

(c) To insure safe use of the industrial starch-modified, the label of the food additive container shall bear the name of the additive “industrial starch-modified,” and in the instance of an industrial starch-modified which is limited with respect to conditions of

use, the label of the food additive container shall contain a statement of such limited use.

[42 FR 14609, Mar. 15, 1977, as amended at 42 FR 49453, Sept. 27, 1977]

§ 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic.

Isoparaffinic petroleum hydrocarbons, synthetic, may be safely used in the production of nonfood articles

Food and Drug Administration, HHS

§ 178.3570

intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The isoparaffinic petroleum hydrocarbons, produced by synthesis from petroleum gases consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 63°–260 °C, as determined by ASTM method D86–82, “Standard Method for Distillation of Petroleum Products,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

Ultraviolet absorbance:

260–319 millimicrons—1.5 maximum.

320–329 millimicrons—0.08 maximum.

330–350 millimicrons—0.05 maximum.

Nonvolatile residue 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application to mineral oil under “Specifications” on page 66 of the “Journal of the Association of Official Agricultural Chemists,” Vol. 45 (February 1962), which is incorporated by reference, disregarding the last sentence of that procedure. For hydrocarbons boiling below 121 °C, the nonvolatile residue shall be determined by ASTM method D1353–78, “Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;” for those boiling above 121 °C, ASTM procedure D381–80, “Standard Test Method for Existent Gum in Fuels by Jet Evaporation,” which are incorporated by reference. Copies may be obtained from the

American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect.

(c) Isoparaffinic petroleum hydrocarbons are used in the production of nonfood articles. The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect, and the residual remaining in the finished article shall be the minimum amount reasonably attainable.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 49 FR 10112, Mar. 19, 1984]

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a)(3).

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
<i>N,N</i> -Bis(2-ethylhexyl)- <i>ar</i> -methyl-1 <i>H</i> -benzotriazole-1-methanamine (CAS Reg. No. 94270–86–7).	For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.
BHA.	
BHT.	
α -Butyl- ω -hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038–95–3.	Addition to food not to exceed 10 parts per million.
α -Butyl- ω -hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003–13–8.	Do.
Castor oil	Do.
Castor oil, dehydrated	Do.